EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name/activity	Total burden hours	Average hourly wage rate *	Total cost burden
Cognitive interviews (HSOPS 2.0 and supplemental items)	90	[a] $35.38	$3,184.20
Pilot test and bridge study	2,297	[b] 34.98	80,349.06
Total	2,387	na	83,533.26

[a] Based on the weighted average hourly wage in hospitals for one physician (29–1060; $101.53), one registered nurse (29–1141; $30.22), one general and operations manager (11–1021; $52.64), and six clinical lab techs (29–2010; $22.34) whose hourly wage is meant to represent wages for other hospital employees who may participate in cognitive interviews

[b] Based on the weighted average hourly wage in hospitals for 1,981 registered nurses, 209 clinical lab techs, 176 physicians and surgeons, and 21 general and operations managers

* National Industry-Specific Occupational Employment and Wage Estimates, May 2013, from the Bureau of Labor Statistics (available at *http://www.bls.gov/oes/current/naics4_621100.htm* [for general medical and surgical hospitals, NAICS 622100]).

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,

Deputy Director.

[FR Doc. 2015–20359 Filed 8–17–15; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0920]

Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems.'' FDA has developed this guidance to inform the coronary and peripheral stent industry about selected updates to FDA's thinking regarding certain non-clinical testing for these devices. While FDA is considering more substantial updates to the ''Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems'' guidance (*http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm071863.htm*), we are issuing this update on select sections in order to notify the industry in a timely manner of our revised recommendations.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Katharine Chowdhury, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 1222, Silver Spring, MD 20993–0002, 301–796–6344, or Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 62, Rm. 3226, Silver Spring, MD 20993–0002, 301–796–6353.

SUPPLEMENTARY INFORMATION:

I. Background

FDA held a public workshop entitled ''Cardiovascular Metallic Implants: Corrosion, Surface Characterization, and Nickel Leaching'' on March 8 and 9, 2012, that provided information on current practices for performing these tests (see *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm287535.htm*). A group of participants from industry, test facilities, and academia provided comments on practices for corrosion testing and nickel ion release testing. Based on the discussion at the workshop, this guidance updates a key aspect of sample conditioning for pitting corrosion testing that is less burdensome, and includes additional information on when galvanic corrosion testing may be omitted with justification, based on information gained from the workshop. This guidance provides updates only for the following topics:

- Pitting corrosion potential
- Galvanic corrosion
- Surface characterization
- Nickel ion release

This guidance provides cross-references and updates to the related

sections of the existing ''Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems'' guidance.

In the **Federal Register** on August 30, 2013 (78 FR 53773), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by September 30, 2013. Four sets of comments were received and, in general, were supportive of the guidance. There were multiple comments regarding the need for clarification of acceptance criteria and the desire for a flow chart to visualize the overall testing paradigm described in the guidance update. In response to these comments, FDA revised the guidance document to include more specific information on acceptance criteria for pitting corrosion and surface oxide properties, as well as a flow chart. General concerns were noted that the guidance modifications might be interpreted to be more burdensome. However, the addition of the flowchart is intended to clarify when testing beyond pitting corrosion testing should be considered, and based on prior experience, it is anticipated that few stents will need further assessment. In addition, there were several comments regarding the lack of utility of post-fatigue pitting corrosion assessment. In response to these comments, as well as discussions at the March 2012 workshop, FDA has removed the suggestion to consider post-fatigue pitting corrosion testing when damage to samples is noted due to fatigue testing. There was also a comment that the 60-day suggested duration for nickel release may be unnecessarily long and burdensome, and in response, FDA has reduced the minimum duration to 30 days if the release rate falls below a predetermined level based on toxicological risk assessment.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on certain non-clinical testing for coronary and peripheral stents. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems '' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1826 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20308 Filed 8–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0640]

Uncomplicated Gonorrhea: Developing Drugs for Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Uncomplicated Gonorrhea: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of uncomplicated gonorrhea. This guidance finalizes the draft guidance of the same name issued on June 19, 2014.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Maria Allende or Joseph Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Uncomplicated Gonorrhea: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the development of drugs for the treatment of uncomplicated gonorrhea.

This guidance describes approaches for trial designs for the evaluation of new drugs for the treatment of uncomplicated gonorrhea. The guidance focuses on the noninferiority trial design and describes an efficacy endpoint for which there is a well-defined treatment effect. The guidance also provides the justification for the noninferiority margin. After careful consideration of comments received in response to the draft guidance issued on June 19, 2014 (79 FR 35172), we added a brief discussion of the potential for pregnant women to be included in specific populations for drug development. In addition, this guidance